

## REMARKS

Claims 1-48 are pending. Claims 1-15 and 24-48 are withdrawn from consideration. Claims 16-23 stand rejected in the current application. The Applicants expressly reserve the right to further prosecute the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 U.S.C. § 120; and 35 U.S.C. § 121.

### *Drawings*

The Examiner objected to the drawings because Figure 30 contained text that appeared to be a description of the drawing and not related to an office-acceptable legend under 37 CFR 1.84(o). A corrected "Replacement Sheet 30/33" is attached. Additionally, the "Brief Description of the Figures" section of the specification has been amended to include the aforementioned description; therefore, no new matter has been added. Acceptance of the changes by the Examiner is respectfully requested.

### *Specification*

The specification was cited for failure to comply with 37 CFR 1.821 through 1.825. A complete sequence listing is attached, and the specification has been amended to reflect the relevant SEQ ID NOS. No new matter has been added. The Applicant believes that all necessary amendments have been made and that the application is now in compliance with 37 CFR 1.821 through 1.825.

### *Claim Rejections – 35 USC § 112*

Claims 16 and 18-23 stand rejected under 35 USC 112, first paragraph, based on the Examiner's contention that the specification fails to comply with the enablement requirement. The Applicants respectfully traverse.

"To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" The Applicant respectfully argues that the amount of experimentation necessary to enable the claimed methods of obtaining predominantly one enantiomer from a mixture of enantiomers is *not* undue for one reasonably skilled in the art when interpreted in light of the guidance provided in the specification.

Claim 16 relates to such a method, comprising the steps of: a. contacting an aqueous fibrous protein solution **wherein the fibrous protein is any fibrous protein** with a solvent that is not miscible with water, **wherein the solvent is any solvent that is not miscible with water**; b. allowing the solution in contact with the solvent to age at about room temperature or under conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f. extracting predominantly a second enantiomer from the interior of the smectic hydrogel.

The examples of solvents that are “not miscible with water” provided in the application - hexane, chloroform, and iso-amyl alcohol - are of varying molecular structures, molecular weights, hydrogen-bonding capabilities, and polarities. They share one feature in common –their immiscibility with water. A person skilled in the art could readily conceive of a myriad of suitable alternatives with similar structural diversity that, with some routine screening as to concentration and temperature, could produce the desired result.

Furthermore, the requirement that the proteins be “fibrous” provides sufficient guidance for an individual skilled in the art to determine a number of enabled alternatives. The specification need not disclose what is well-known in the art; fibrous proteins are long filaments, generally water-insoluble, with protruding hydrophobic R groups. The number of amino acid residues found in fibrous proteins is limited, and oftentimes sequences are repeated. Limiting the claims to the group of fibrous proteins consisting of silk, collagens, keratins, actins, chorions, and seroins would unreasonably narrow the claims as compared to the invention taught and enabled by the Applicant. The Applicants respectfully maintain that the fibrous protein sequences need not be restricted to the specific classes cited by the Examiner in order for the claimed methods to be enabled by the instant application and the knowledge of one of ordinary skill in the relevant art at the time the application was filed. Indeed, the specification teaches that the sequences employed in the present invention are intended to be “loosely-based” (page 23, line 19) on these natural fibrous proteins and that the ultimate materials properties can be

manipulated based on the selection of sequence patterns (page 26, lines 31-32). Additional guidance as to the protein sequences ideal for the present invention can be found on page 23, lines 20-22: “individual oligopeptides within each class incorporate *simplified versions* of patterned amino acid motifs found in each protein type” (emphasis added). Not only are the general features of fibrous proteins known to those of ordinary skill in the art, but the specification outlines that the recited sequences may be simplified.

With knowledge of the general structure of fibrous proteins, and the direction provided by the specification, a person of ordinary skill in the art could engineer peptides with specific sequence patterns that, with only the need for routine experimentation, could form the smectic hydrogels used in the claimed methods. Determining the concentrations and temperatures under which each engineered fibrous protein would self-assemble, and under which conditions enantiomers could be separated, would require no more than routine screening experiments with a limited number of easily assessed variables. Moreover, the specification discloses the necessary experimental methods; one would merely need to conduct the experiments. Therefore, the Applicant respectfully argues that the experimentation necessary to make and use the claimed scope of the present invention is not undue.

Accordingly, the Applicants respectfully request withdrawal of the claim rejections under the enablement requirement of 35 U.S.C. § 112¶1.

### **FEES**

The Applicants believe no fee is required in connection with the filing of this paper. Nevertheless, the Commissioner is hereby authorized to charge any fees due in connection with the filing of this Response to our Deposit Account, **No. 06-1448**, reference **TUV-031.01**.

### CONCLUSION

The Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 832-1000.

Respectfully submitted,  
Foley Hoag LLP

155 Seaport Boulevard  
Boston, MA 02210

Telephone: (617) 832-1000  
Telecopier: (617) 832-7000

Date: July 22, 2008

By: /Dana M. Gordon/  
Dana M. Gordon, Ph.D.  
Reg. No. 44,719  
Attorney for Applicants